Committee scored percentage consensus based on three categories: "large consensus", "moderate consensus", "minimum consensus".
Results: All chapters were voted on by at least 75% of the members, and the majority was voted on by more than 85%. The total number of the voted sentences was 207. Of the 207, 86% achieved "large consensus", 13% achieved "moderate consensus", and only 3 (1%) resulted in "minimum consensus". No statement was disagreed by more than 50% of members.
Conclusions: This Consensus Conference represents an expertise opinion process that may be useful to define guidelines for staging and treatment of rectal cancer and may help to draw future programs and investigational protocols throughout Europe.

6045 POSTER

Safety analysis of starpan (star-02) study with panitumumab, 5-fluorouracil, oxaliplatin and concurrent radiotherapy in locally advanced rectal cancer

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Background: The aim of this phase II study was to assess the activity of preoperative external radiotherapy combined with panitumumab, oxaliplatin and 5-fluorouracil in locally advanced rectal cancer patients (pts).
Materials and Methods: Pts entering the study had histologically-proven rectal adenocarcinoma, either cT3N+ or cT4N-/+ stage, with location <12 cm from the anal margin. Panitumumab was administered at a dose of 6 mg/kg IV, 2 weeks before the start of chemoradiotherapy, and then in combination with chemoradiotherapy, 3 times every 2 weeks. 5-fluorouracil and oxaliplatin were administered according to established schedule of STAR-01 Study (oxaliplatin 60 mg/m^2 IV weekly six times, 1 h after the panitumumab infusion, and 5-fluorouracil 225 mg/m^2/day continuous infusion IV days 1−38). Radiotherapy was delivered at a dose of 50.4 Gy in daily fractions of 1.8 Gy. Rectal surgery was performed 7−8 weeks after the end of neoadjuvant treatment. Eight courses of adjuvant chemotherapy with FOLFOX4 plus panitumumab at the dose of 6 mg/kg, every 2 weeks, were given post-surgery. The main study endpoint was complete pathological response rate.
Results: From February 2007 to April 2009 fifty-one pts were enrolled (9 too early pts). Characteristics of the 42 evaluated pts were: male 28 (66.7%), female 14 (33.3%); median age 60 (37−78); median Karnofsky PS 100 (70–100); stage: cT3N+ 31 (73.8%), cT4N− 3 (7.1%), cT4N+ 8 (19.1%). Thirty-three pts have completed neoadjuvant treatment and 30 have undergone surgery (12 pts ongoing). The most frequent grade 1−2 side effects were acneiform rash (56.7%), diarrhea (27%) and fatigue (8%). Grade 3−4 diarrhea was found in 32.4% of pts, and grade 3 cutaneous toxicity in 43.3%. No grade 3 hematological toxicity was found. The median cumulative dose of delivered radiotherapy was 50.4 Gy. The planned dose of panitumumab, 5-fluourouracil and oxaliplatin was administered in 78.8%, 63.6% and 69.6% of pts, respectively.
Conclusions: These early results demonstrate that panitumumab can be added to 5-fluorouracil/oxaliplatin-based chemoradiotherapy without compromising the concurrent radiotherapy dose. This combination treatment is associated with high incidence of grade 3−4 diarrhea.

6046 POSTER

Predictive role of 18f-fdg-pet in locally advanced rectal cancer patients treated with neoadjuvant chemo-radiotherapy (Bologna Project)

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Background: The identification of predictive response factors in locally advanced rectal cancer patients (pts) treated with neoadjuvant chemo-radiotherapy (CRT) can direct the choice of therapeutic strategy. The aim of the study was to evaluate the predictive value of basal and pre-surgical 18F-FDG-PET (PET).
Materials and Methods: Pts entering the study had cT3-T4 N-/+ rectal adenocarcinoma <12 cm from the anal margin. CT consisted in 5-fluorouracil with or without oxaliplatin; RT was delivered up to a dose of 50.4 Gy in daily fractions of 1.8 Gy; rectal surgery was performed 6−8 weeks after the end of CRT. PET was performed at initial diagnosis and before the surgery. Standard Uptake Value (SUV1 = basal PET, SUV2 = pre-surgery PET) was determined from the most active tumor site. The pathological examination of surgical specimens included the Tumor Regression Grade (TRG) evaluation according to the Dworak grading. Responder pts were defined as TRG4 = complete regression, TRG3 = good regression, TRG2 = moderate regression, and non-responder pts were defined as TRG1 = minor regression, TRG0 = no regression.
Results: Eighty pts were evaluated between June 2003 and February 2009. The pt characteristics were: 55 (68.7%) males, 25 (31.3%) females; median age 65 years (33−80); stage: 36 (45%) cT3N-M0, 33 (41.3%) cT3N+M0, 6 (7.5%) cT4N-M0, 5 (6.2%) cT4N+M0. The pathological responses were: TRG1 16 (20%) pts, TRG2 28 (35%), TRG3 20 (25%), TRG4 16 (20%). The SUV1 and SUV2 cut-off related to TRG are 19 and 4.9, respectively, was identified with ROC analysis. In 53 (66.3%) pts SUV1 was $\leqslant$19 (low) and in 27 (33.7%) it was >19 (high). The low SUV1 value was significantly correlated with TRG2−4 ($p = 0.002$). In 53 (66.3%) pts the SUV2 was $\leqslant$4.9 (low) and in 27 (33.7%) it was >4.9 (high). The low SUV2 value was significantly correlated with TRG2−4 ($p < 0.0001$). In multivariate analysis, TRG2−4 was statistically correlated with SUV1 ($p = 0.010$) and SUV2 ($p = 0.018$).
Conclusions: These results suggest that a low baseline SUV value and a low pre-surgical SUV value could predict the pathological response in locally advanced rectal cancer pts treated with neoadjuvant CRT. In this pt setting, the PET evaluation should be further investigated in order to establish the treatment strategy.

6047 POSTER

Development of nomograms for prediction of pathologic complete response in locally advanced rectum cancer: a multicentric study using PET before, during and after neoadjuvant chemoradiotherapy

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Purpose: The prediction of pathologic complete response (pCR) after preoperative chemoradiotherapy (CRT) might be helpful for selecting rectal cancer patients in which a less invasive surgery or a "wait and see policy" would be possible. A prediction of the pathological response already during CRT, as opposed to after CRT, would be more attractive, because it could enable response-guided modifications of the treatment protocol. In this study, data were prospectively collected at 3 different institutions. Three different imaging time points were analyzed for their predictive value: pre-CRT, during CRT and after CRT, just before surgery.
Methods: The datasets with both clinical and imaging variables from 3 different institutions were merged to have a statistical weight. A total of 64 patients were treated with long-term chemoradiotherapy (CRT). For all patients, three PET-CT scans were acquired (before CRT, during CRT, after CRT just before surgery). Clinical variables included age, sex, WHO performance status, BMI, cTNM stage. For PET-analyses, the tumors were semi-automatically contoured using standardized uptake-value (SUV) thresholding. Imaging variables consisted of tumor dimensions (GTV, maximal diameter, distance from anal verge) and metabolic activity of the tumor corrected by blood glucose (SUVmean, SUVmax). In addition, for the follow-up PET scans, all relative differences (response indices, RI) were also included in the evaluation. Multivariate analysis was performed with a 2-norm support vector machine (SVM). Performance of the model was expressed as the area-under-the-curve (AUC) of the receiver-operating-characteristic (ROC) curves and assessed with leave-one-out (LOO) cross-validation. Also, all output was converted to nomograms.
Results: For 23% of the patients, CRT resulted in a pCR. Based on the AUCs (Mean $\pm$SD) of the ROC-curves, the model containing PET variables during treatment reached the highest training performance (0.82 ± 0.07) when compared to pretreatment (0.75 ± 0.08) and pre-surgical (0.72 ± 0.10) models. For PET-imaging during treatment, these variables were predictive (ranked by their importance): response index of SUVmax during CRT (0.28), cT-stage (−0.22), cN-stage (−0.18).
Conclusion: The prediction of pCR based on both clinical variables and PET variables assessed early during treatment was found to be most accurate based on the multivariate analysis. Easy to use nomograms will be presented. A prospective validation of the model is underway and the